K120089

MAR 13 2013

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 02/06/2013

1. Submitter

Biogenesis Co., Ltd.
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2. U.S Agent/Contact Person

LK Consulting Group USA, Inc.
1515 E Katella Ave Unit 2115, Anaheim, CA 92805
Priscilla Chung
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3. Device

Trade Name: Biogenesis™ Implant System - Aticon
Common Name: Dental Implant System
Classification Name: Endosseous Dental Implant System
Product Code: DZE, NHA
Classification regulation: 21CFR872.3640

4. Predicate Device:

GSIII internal fixture by Osstem (K082213)
Prima Connex internal fixture by Lifecore (K051614)
Implantium internal abutment by Dentium (K052823)
EZ PLUS Implant system by Megagen (K070562)

5. Description:

The Biogenesis™ Implant System replaces the root of a missing tooth and is made from surgical grade titanium alloys. The Biogenesis™ Implant System is comprised of two components, implant, which is the portion that goes into the jaw bone, and the abutment, which fits into the implant and provides a solid base for a crown or a denture.

6. Indication for use:

The Biogenesis Implant System - Aticon is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System is for single and two stage surgical procedures. It is intended for delayed loading.

7. Basis for Substantial Equivalence

The Biogenesis™ Implant System is substantially equivalent to previously marketed devices. The design features and sizing of the components were also compared and the Biogenesis™ Implant System found to be substantially the same as these systems. It is manufactured from the same materials and is indicated for the same intended uses as these systems. There are no significant differences between the Biogenesis™ Implant System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

8. Non-clinical Testing

The following non-clinical testing was conducted to validate its safety.

- Surface Roughness Analysis and Chemical Analysis to verify cleanness after surface treatment.
- Packaging and Sterilization Validation Tests:
  Sterilization validation was provided for the components that are provided sterile and also for the components that are provided non-sterile and intended to be sterilized by the end user.
- Biocompatibility Test: ISO 10993-5 Cytotoxicity Test

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium alloys and have the same surface treatments. The subject and the predicate devices encompass the similar range of physical dimensions, including diameter and length of the implants, and diameter and height of the abutments.

Overall, Biogenesis™ Implant System has the following similarities to the predicate device:
* has the same intended use,
* uses the same operating principle,
* incorporates the same basic design,
* incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the Biogenesis™ Implant System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Biogenesis Company, Limited
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Incorporated
1515 East Katella Avenue, Unit 2115
ANAHEIM CA 92805

Re: K120089
Trade/Device Name: Biogenesis™ Implant System - Aticon
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 4, 2013
Received: March 7, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120089

Device Name: Biogenesis™ Implant System - Aticon

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Prescription Use __√__ **(Per 21 CFR 801 Subpart D)** **AND** **Over-The Counter Use**____ **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA
Mary S. Runner -S
2013.03.12 12:08:20 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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